K063402

INTELLIGENT HEARING SYSTEMS

510(k) Summary

DEC 1 1 2006

Prepared By:	Intelligent Hearing Systems 6860 SW 81st Street Miami, FL 33143
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Contact Person:	Edward Miskiel
Date Summary prepared:	October 31, 2006
Name of the Device:	TM-Wick Electrode
Common Name:	Disposable Extra-Tympanic Electrode for Electrocochleography
Classification Name:	Cutaneous Electrode (per CFR 882.1320)
Classification Product Code:	GXY
Regulatory Class:	Class II
Predicate Device:	Bio-Logic TM-ECochGtrode (K944314)
Device Description:	IHS TM-Wick Electrodes are non-invasive, cutaneous devices used in the acquisition of electrocochleography (ECochG) signals from the tympanic membrane for the purpose of monitoring and recording. These extra-tympanic electrodes are inserted into the ear canal to make contact with the tympanic membrane for acquiring the ECochG data. The electrodes are biocompatible, non-sterile, single patient use, disposable devices.
Intended Use:	The IHS TM-Wick Electrode is intended for non-invasive use in acquiring ECochG data on patients of all ages, for the purpose of monitoring and recording in the diagnosis of cochlear and auditory disorders. This is the **same intended use** as that of the predicate device.

Technological Characteristics:

Electrocochleography (ECochG) is a method to acquire auditory evoked potential responses from the cochlea and auditory nerves by providing sound stimulation to the patient's ear. The amplitude, latencies, and relationship of the various ECochG signal waves can be used to diagnose certain pathological conditions. Its clinical applications include contributing to the diagnosis of Meniere's disease, providing an enhanced Wave I of the Auditory Brainstem Response (ABR), and monitoring of cochlear and auditory nerve function during surgery.

Due to the low amplitudes of ECochG signals, standard surface electrodes cannot be used to acquire ECochG recordings. The electrodes must be placed as close as possible to the cochlea to record such signals. There are two general approaches for recording ECochG: Transtympanic (TT) and Extratympanic (ET). TT ECochG is an invasive procedure that involves passing a needle electrode through the tympanic membrane (TM) to rest on the cochlear promontory. ET ECochG is a non-invasive procedure wherein recordings are performed with an electrode resting against the skin of the ear canal or surface of the tympanic membrane. For the latter recording site making contact with the tympanic membrane, the procedure is also commonly referred to as "Tympanic" (TM) ECochG.

There are three main types of electrodes currently available for use in ECochG testing: TT needle electrodes, TM electrodes, and tiptrodes. While TT needle electrodes provide the highest quality responses, they are invasive, painful to the patient, and require the assistance of a trained physician in a medical setting. Tiptrodes are gold foil-wrapped polyurethane-foam eartips that act as both inverting electrode and the stimulus delivery device. These electrodes are covered in conductive gel/paste and simply placed in the ear canal. Although this type of electrode is non-invasive and painless to the patient, the acquired signal components tend to be smaller, less robust, and have poorer quality signal-to-noise ratios (SNR).

As mentioned, TM electrodes are inserted into the ear canal to make contact with the surface of the tympanic membrane for recording ECochG data. TM electrodes offer the best compromise between the TT needle electrode and the tiptrode. The acquired signal component magnitudes, SNR, and waveform patterns are well preserved in the TM recordings when compared to the TT measurements. In addition, this type of electrode is also non-invasive and causes minimal discomfort to the patient, and can be applied by an audiologist without sedation or local anesthesia. Typically, a TM electrode consists of a thin, bare, conducting lead wire (usually made of pure Silver and/or Silver Chloride) insulated inside of a flexible silicone tubing, with the end of this wire attached to a biocompatible foam rubber or cotton tip impregnated with a conductive gel, or the wire is simply encased within a conductive hydrogel molded tip. This silicone tubing and pre-soaked foam rubber, cotton, or hydrogel tip are the only portions of the electrode to maintain skin contact with the patient (i.e., the ear canal and tympanic membrane). Usually, TM electrodes are non-sterile and disposable.

The IHS TM-Wick Electrode is a non-invasive, TM ECochG electrode which is biocompatible, pre-wired, non-sterile, for single patient use, and disposable. The electrode features a fine Silver/Silver Chloride (Ag/AgCl) wire attached to a soft cotton tip (i.e., wick) pre-soaked in a highly conductive, low impedance electrode gel/saline solution, which is hypoallergenic, non-irritating, bacteriostatic, water soluble, non-staining, and non-gritty. The conductive gel reduces the impedance of the contact between the electrode surface and the skin. The Ag/AgCl wire is encased inside of a thin, soft, flexible silicone tubing which is resilient, stretchable, non-corrosive, and inert. This tubing's small size and characteristics provide for ease of insertion and removal, as well as patient comfort and safety.

The other end of the Ag/AgCl wire is permanently adhered/soldered to an electrode cable lead wire. The solder joint is then covered by a heat shrink tubing so as not to allow exposure of the lead wire, as well as to provide strain relief. The electrode cable lead is terminated on the opposite end using two industry standard 1.5mm (0.06in) molded DIN safety socket connectors, which are subsequently used to interface to the monitoring device. For electrical safety, these connectors do not allow accidental connection to an A/C wall electrical outlet.

The silicone tubing, cotton, and conductive gel/saline solution that come in contact with the patient all meet the required electrode biocompatibility testing criteria specified in the ISO 10993-1 standard for skin contact, and are non-irritating, non-sensitizing, and non-cytotoxic to the skin.

A typical IHS TM-Wick Electrode will come fully assembled and pre-wired in individual packaging with appropriate instructions for use, contact information, part/lot numbers, storage information, and warnings, including the precaution statement: ***Federal law restricts this device to sale by or on the order of a physician. Single patient use only.***

Safety & Effectiveness:

IHS considers the TM-Wick Electrode to be as safe and effective as the Bio-Logic TM-ECochGTrode (K944314). The TM-Wick Electrodes are non-invasive, biocompatible, non-sterile, single patient use, disposable devices.

The soft silicone tubing and conductive gel/saline soaked cotton wick tip are the only portions of the electrode to maintain skin contact with the patient (i.e., the ear canal and tympanic membrane). The conductive gel used on the cotton wick tip of the electrode is a multi-purpose saline electrode gel which is suitable for all bio-potential recordings and meets all the standards for the ideal saline electrode gel; namely it is highly conductive, hypoallergenic, non-irritating, bacteriostatic, water soluble, non-staining, and non-gritty.

All components used to manufacture the TM-Wick Electrodes that come into contact with the patient meet the required electrode biocompatibility testing criteria specified in the ISO 10993 standard for skin contact, namely:

- Cytotoxicity (ISO 10993-5)
- Skin irritation (ISO 10993-10)
- Skin sensitization (ISO 10993-10)

The electrode lead wire assembly is in compliance with the requirements of the FDA/CDRH 21 CFR 898 Performance Standard for Electrode Lead Wires and Patient Cables. The lead wire is terminated on the opposite end using two industry standard 1.5mm DIN safety connectors which are subsequently used to interface to the monitoring device. These connectors do not allow connection to an A/C electrical outlet.

These electrodes will include the precaution statement: ***Federal law restricts this device to sale by or on the order of a physician. Single patient use only.***

Substantial Equivalence Based on Assessment of Performance Data:

With respect to electrocochleography (ECochG) testing, the IHS TM-Wick Electrode device is substantially equivalent to the TM-ECochGtrode disposable extra-tympanic electrode for ECochG, marketed by Bio-Logic with FDA 510(k) clearance number K944314. Comparisons of general and performance specification parameters are shown in Table 1 below.

SPECIFICATIONS

Parameter	Predicate Device *Bio-Logic TM-ECochGtrode (K944314)*	Device Under Current 510(k) Review *IHS TM-Wick Electrode*
Intended Use	Non-invasive acquisition of ECochG data on patients of all ages	Same
Indications for Use	Monitoring & recording in the diagnosis of cochlear and auditory disorders	Same
Target Population	All Ages	Same
Design	Thin, bare, conducting Silver/Silver-Chloride (Ag/AgCl) wire insulated inside of a flexible silicone tubing, with the end of wire encased within a conductive hydrogel molded tip Requires attachment of separate external lead wire to the connector end of electrode Fully assembled in individual packaging Single patient use, disposable devices	Thin, bare, conducting Silver/Silver-Chloride wire insulated inside of a flexible silicone tubing, with the end of wire attached to a soft cotton tip pre-soaked in a conductive electrode gel/saline solution Electrode cable lead is terminated on the opposite end using two industry standard 1.5mm (0.06in) molded DIN safety socket connectors, used to interface to the monitoring device Fully assembled and pre-wired in individual packaging Single patient use, disposable devices
Materials	Silicone tubing, conductive hydrogel molded tip, Silver/Silver-Chloride wire, electrode cable lead connector	Silicone tubing, cotton wick tip, conductive gel/saline, Silver/Silver-Chloride wire, electrode cable lead, molded DIN safety socket connectors
Sterility	None Required	Same
Biocompatibility	Completely Biocompatible	Same
Anatomical Sites	Ear Canal & Tympanic Membrane	Same
Where Used	Clinical Setting	Same

Safety	None Specified	All components that come into contact with the patient meet the biocompatibility criteria specified in the ISO 10993 standard for skin contact (cytotoxicity, skin irritation, & skin sensitization). Electrode lead wire assembly is in compliance with the requirements of FDA 21 CFR 898 standard, namely the lead wire is terminated using industry standard 1.5mm DIN safety socket connectors which do not allow connection to an A/C electrical outlet. Silicone tubing's small size and characteristics provide for ease of insertion and removal, as well as patient comfort and safety. Approximately 1/3 smaller in size diameter than the predicate's tubing.

Table 1: General and performance specifications of predicate device & current device under 510(k) review.

Declaration of Conformity:

As required by our risk analysis, all verification and validation activities have been performed for the IHS TM-Wick Electrode device by designated individuals at Intelligent Hearing Systems. The results have demonstrated that all predetermined acceptance criteria have been met, in accordance with our ISO-13485 quality system. All records, including Device Master Records and Design History Files, are available for review upon request.

Edward Miskiel, Ph.D.
President & CEO

10/31/06
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Intelligent Hearing Systems
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DEC 1 1 2006

Re: K063402
Trade/Device Name: TM-WICK Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 31, 2006
Received: November 9, 2006

Dear Mr. Miskiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K063402

Device Name: **TM-Wick Electrode**

Indications for Use:

The IHS TM-Wick Electrode is intended for non-invasive use in acquiring electrocochleography (ECochG) data on patients of all ages, for the purpose of monitoring and recording in the diagnosis of cochlear and auditory disorders. The electrodes are biocompatible, non-sterile, single patient use, disposable devices.

The IHS TM-Wick Electrode is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's, or physician's office or other appropriate setting.

The anatomical sites of contact of the IHS TM-Wick Electrode for ECochG testing are the patient's ear canal and tympanic membrane (with the contact objects being a thin, soft, flexible silicone tubing and a cotton wick tip which is pre-soaked in a conductive gel/saline solution).

These electrodes will include the precaution statement: ***Federal law restricts this device to sale by or on the order of a physician. Single patient use only.***

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X
(Per 21 CFR 801.109)

James K. Kana, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
510(k) Number K063402